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Compatibility of Electrolytically Produced Sodium Hypochlorite Solutions on Long-Term Implanted Dialysis Catheters

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Abstract

More than 20% of the world's population use a catheter for dialysis, despite guidelines limiting their use. Although the structure and design of the catheters differ by manufacturer, the material used in central venous catheters and peritoneal dialysis catheters are the same across manufacturers. Given the long-term use of these catheters in the dialysis population, the good compatibility of the antiseptics and disinfectants used on the catheters is imperative to prevent failure and cracking of the catheter material. Tensile strengths of commercially available catheters were measured after exposure to commonly used disinfectants. The tensile strength was then compared between the catheters by analyzing the displacement vs. force (N) curves produced during the evaluation. A total of 44 catheter lumens were evaluated. The electrolytically produced sodium hypochlorite solution, Alcavis 50/ExSept Plus, was the only solution shown to be compatible with all three catheter materials resulting in a deviation of less than 10% for each of the different catheter types. Electrolytically produced sodium hypochlorite solutions were the only solutions in this study that did not alter the physical properties of any of the catheters after long-term exposure.

Long-term implanted catheters continue to be an important tool for the administration of dialysis. In the United States, for example, there is a prevalence of 20% catheter use for hemodialysis (HD), while all peritoneal dialysis (PD) patients require an implanted catheter [1]. This results in more than 90,000 dialysis patients in the United States using a long-term catheter. Prevalence of long-term catheter use throughout the world may be even greater dependent on the proportion of patients on PD and availability of vascular surgical teams to prepare fistulas [1, 2].

Patients with either a HD central venous catheter (CVC) or PD catheter (PDC) are at an elevated risk of skin infection at the exit site of the catheter or below the skin in the catheter tunnel. CVCs are at risk of bacteremia, if bacteria are introduced into the lumen of the catheter and migrates into the blood stream. Similarly, PDCs are at risk of peritonitis if bacteria enter the inner lumen of the catheter and reach the peritoneal cavity.

Proper handling of the catheter and aseptic technique are required to reduce risks of infection. Routine dressing changes, antisepsis at the exit site, cuffed catheters, proper disinfection prior to accessing and careful manipulation of the catheter are powerful tools for reducing exit site, tunnel and blood stream infections. Maki showed that in the short-term, approximately 1 week, bacteremia is likely a result from the insertion procedure with a lesser risk from hub contamination [3]. However, Sitges-Serra and Linares et al. suggest that the risks of bacteremia are greatest as a direct result of hub contamination. This was their conclusion in a study population that had catheters in place on average for approximately 3 weeks [4, 5].

Several studies have demonstrated that the use of electrolytically produced sodium hypochlorite (ESH) solutions for the chronic care of implanted dialysis catheters (CVC and PDC) can reduce the rate of infection. Benefits of the use of ESH for exit site antisepsis for CVC care has recently been demonstrated by Astle and Jensen [6], while Mishkin et al. [7], Wahdwa et al. [8] and Mendoza [9] have demonstrated the benefits of ESH for routine PDC exit site care. Furthermore, advantages using ESH solutions in reducing bacteremia and peritonitis rates have also been demonstrated by Astle et al. [6] and Mishkin et al. [7].

The benefits of ESH for routine long-term catheter care at the exit site and connection sites (ex. hub and cap disinfection and transfer set change disinfection) have been clinically demonstrated. However, a common obstacle of good catheter care is the compatibility of an antiseptic or disinfectant with the catheter material. The Center for Disease Controls' Guideline for the Reduction in Intravascular Catheter Related Infections, recommendations for the routine care of 'Dialysis CVC' states: 'ensure the cleaning solutions are compatible with the catheter materials' [10].

CVC and PDC exit site care is performed thrice weekly and daily, respectively. Disinfection of the catheter hubs and connectors is also performed before and after every treatment. Given a life expectancy of a catheter of 6 months, this results in a minimum of 78 applications of the antiseptic or disinfectant to both the skin and catheter material. It is imperative that the antiseptic or disinfectant be safe and effective to the patient as well as compatible with the catheter materials. There is ample evidence that ESH solutions are safe, non-irritating and non-sensitizing, and effective [6, 7, 11–13]. The compatibility of the catheter materials with different antiseptics and disinfectants will be reviewed.

PDCs are usually made out of silicone as are the transfer sets used with PDCs. CVCs however are usually made from one of three different materials: (1) silicone (similar to PDC); (2) Tecoflex® polyurethane (Noveon), or (3) Carbothane® polyurethane/polycarbonate copolymer (Noveon) [14]. Although the structure and design of the catheters differ by manufacturer, the material used in CVC and PDC catheters are the same across manufacturers.

The safety testing of catheters is similar around the world and follows ISO 1055501:1995(E) guideline. The use of antiseptics and disinfectants on catheters potentially affect the safety of the catheter by degrading the structural integrity of the catheter material, (ex. lumen) or the integrity at each juncture of the catheter (ex. luer connector to extension, extension to hub, hub to lumen, etc). ESH is listed as a recommended disinfectant/antiseptic by numerous catheter manufacturers, having passed the ISO standards above, for all three available catheter materials. This makes ESH unique in that it is the only antiseptic routinely used that is compatible with all materials. As a rule of thumb, it is recommended that povidone iodine only be used with polyurethane based catheters and alcohol containing products only be used with silicone based products. The newer material Carbothane copolymer claims to be compatible with all antiseptics and disinfectants commonly used.

A modified evaluation of the ISO standards was performed in order to compare the affects of ESH on the three different materials used for dialysis catheters. In addition, we evaluate the affects of different antiseptics on dialysis catheters to assess changes in physical properties such as lumen strength.

Method

Exposure to Disinfectant

Catheter lumens were cut at the juncture and completely submerged in the test disinfectant for 48 h. Disinfectant was flushed through each lumen to ensure the disinfectant contacted both the external and internal part of the lumens. After 48 h, each catheter lumen was removed from the disinfectant and rinsed with normal saline. Table 1 displays the catheter model, manufacturer and material. Table 2 shows the catheter models and disinfectants tested.

Tensile Strength Testing

Tensile strength was evaluated using an ATS 900 (Applied Test Systems) device which was connected to an IBM PC for data acquisition (fig. 1). Unique grips were made in order to properly grasp both ends of the lumen to minimize any damage at the connection sites (fig. 2). A segment of 6 cm was used for each catheter. The ATS 900 was then programmed to elongate the lumens at a rates of 25 mm per minute. As the lumen was being stretched, displacement (mm) and force (N) were recorded every second and stored in a database on the PC.

Three samples of each catheter type in each solution were evaluated.

Table 1. Catheters tested

Catheter	OEM	Material	Subclass
Hemoglide®	Bard®	Polyurethane	Tecoflex®
Hemosplit®	Bard®	Polyurethane	Carbothane®
Hickman®	Bard®	Silicone	–
Cannon Cath II®	Arrow®	Polyurethane	Tecoflex®
Xpresso®	Spire®	Silicone	–

Carbothane® and Tecoflex® are manufactured by Noveon Thermedics Polymer Products.

Table 2. Solutions tested

Catheter	Saline (Control)	Alcavis 50/ ExSept Plus	Povidone iodine	Alcohol 70% IPA
Hemoglide®	Y	Y	–	Y
Hemosplit®	Y	Y	Y	Y
Hickman®	Y	Y	–	Y
Cannon Cath II®	Y	Y	–	–
Xpresso®	Y	Y	–	Y

Analysis

Tensile strength was compared between the catheters by analyzing the displacement vs. force (N) curves produced during the evaluation. In order to evaluate differences caused by exposure to different antiseptics/disinfectants, the deviation percentage of the resultant force at each elongation length were calculated. An average deviation greater than 10% when compared to the control lumen (only exposed to saline) was considered significantly affected by the antiseptic/disinfectant. Catheters were only compared with the same catheter exposed to saline, not across different catheters.

Results

A total of 44 catheter lumens were evaluated (only two Hemosplit® with povidone iodine were evaluated). The average maximum displacement for each catheter type in each solution is presented in table 3. Significance in displacement was reached for Alcavis 50 on the Cannon Cath II® catheter, however this is not significant since the catheter exposed to Alcavis 50 ESH had reached maximum displacement as limited by the ATS 900 system.

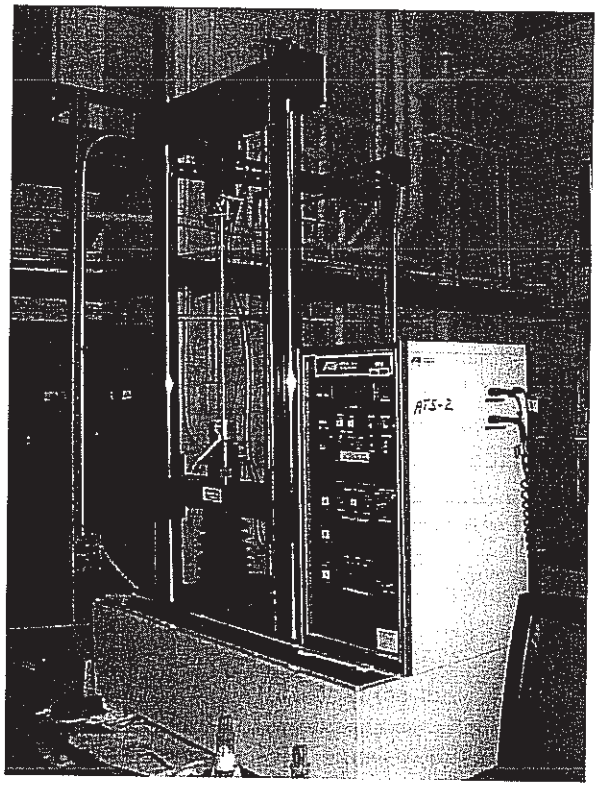

Fig. 1. ATS 900 meter with computer.

The final force (N) reached as the catheters were stretched is displayed in table 4. Significance was reached for both polyurethane based materials tested that were exposed to alcohol. The Carbothane yielded a greater force vs. displacement curve than Tecoflex, although only achieving 40% of the force for the same catheter exposed to saline or Alcavis 50. The Carbothane catheter appears to be stronger than the Tecoflex catheter.

Evaluation of the curves were performed by assessing the deviations from the control. Table 5 shows the average deviations from the saline control. Again, the Carbothane and Tecoflex catheters exposed to 70% isopropyl alcohol resulted in significant deviations from the control by approximately 50%. None of the other solutions tested affected the characteristic displacement vs. force curve by more than 10% on average.

The ESH solution Alcavis 50 was compatible with all three catheter materials resulting in a deviation of less than 10% for each of the different catheter

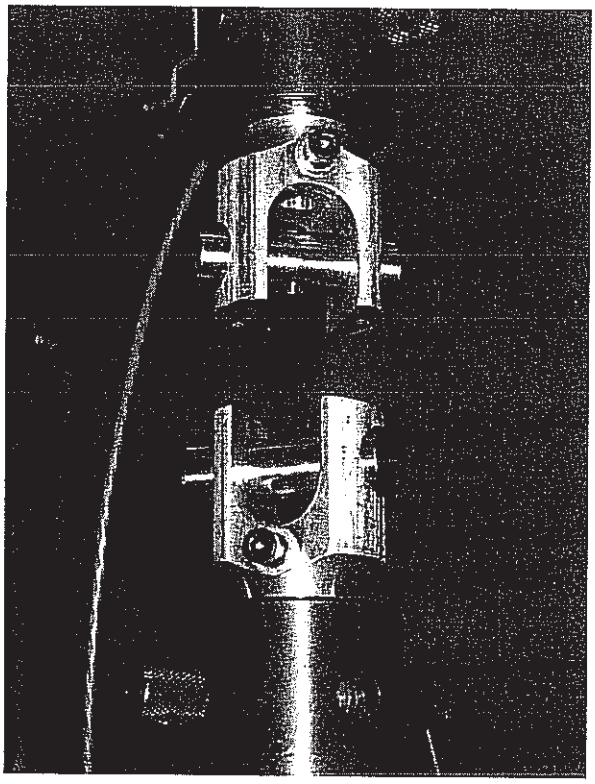

Fig. 2. Unique grips were designed to minimize tearing at the connection sites.

Table 3. Catheter displacement (mm)

Catheter	Material	Saline (Control)	Alcavis 50/ ExSept Plus	PI	Alcohol
Hemoglide® (Bard)	Polyurethane Tecoflex®	494 ± 93	565 ± 9	–	469 ± 63
Hemosplit® (Bard)	Polyurethane Carbothane®	310 ± 72	323 ± 86	362 ± 65	374 ± 21
Hickman® (Bard)	Silicone	496 ± 90	456 ± 37	–	370 ± 83
Cannon Cath II® (Arrow)	Polyurethane Tecoflex®	512 ± 29	462 ± 23*	–	–
Xpresso® (Spire)	Silicone	374 ± 38	466 ± 66	–	397 ± 59

*$p < 0.05$, compared to saline control.

Table 4. Catheter resultant forces (N)

Catheter	Material	Saline	Alcavis 50 (ExSept Plus)	PI	Alcohol
Hemoglide® (Bard)	Polyurethane Tecoflex®	242 ± 14	228 ± 4	–	51 ± 6*
Hemosplit® (Bard)	Polyurethane Carbothane®	215 ± 9	211 ± 23	229 ± 32	81 ± 9*
Hickman® (Bard)	Silicone	54 ± 7	54 ± 5	–	49 ± 5
Cannon Cath II® (Arrow)	Polyurethane Tecoflex®	268 ± 27	254 ± 37	–	–
Xpresso® (Spire)	Silicone	82 ± 5	84 ± 8	–	78 ± 7

*$p < 0.05$, compared to saline control.

Table 5. Average deviations: comparing the curves

Catheter	Material	Saline	Alcavis 50 (ExSept Plus)	PI	Alcohol
Hemoglide® (Bard)	Polyurethane Tecoflex®	NA	8.1 ± 5.4	–	52.5 ± 8.7*
Hemosplit® (Bard)	Polyurethane Carbothane®	NA	1.1 ± 14.4	7.0 ± 9.5	49.3 ± 5.7*
Hickman® (Bard)	Silicone	NA	7.0 ± 9.6	–	1.9 ± 9.4
Cannon Cath II® (Arrow)	Polyurethane Tecoflex®	NA	7.7 ± 5.2	–	–
Xpresso® (Spire)	Silicone	NA	0.5 ± 16.1	–	7.8 ± 17.2

*>10% deviation, considered significant.

types. Figures 3, 4, and 5 display the resultant curves for the different antiseptics and disinfectants. You will notice that the resultant curve for ESH is nearly identical to the curves from those catheters exposed to normal saline for all three materials tested.

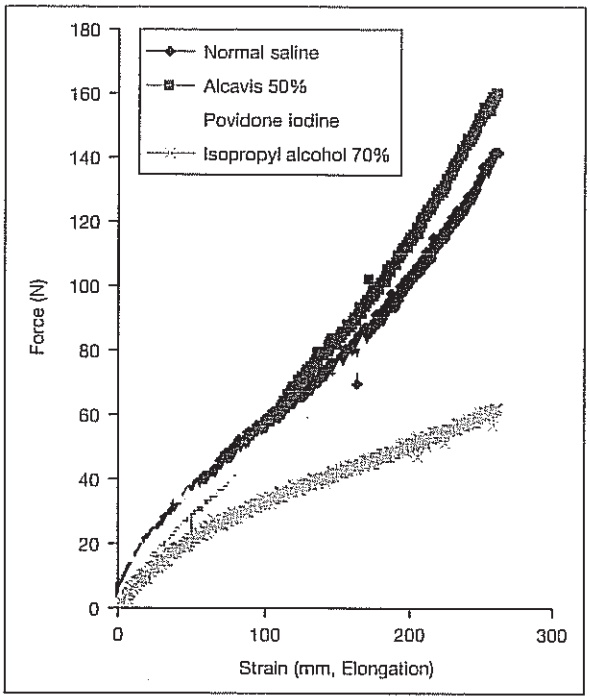

Fig. 3. Bard Hemosplit® Carbothane® catheter in different disinfectants.

Discussion

Concerns of incompatible antiseptic and disinfectants are commonly raised by catheter manufacturers, clinic staff and even regulatory agencies such as the CDC [10]. The frequency of reported complications is low, however, this does not mean catheter degradation is not a common problem in the clinics, only that it is not commonly reported.

It is common that a clinic will have many patients from several different nephrologists, different hospitals and different interventional radiologist or surgeons. It is therefore, very likely that there will be several different catheters from different manufacturers and of different materials. This is where the risk of degradation is greatest since identifying the catheter material is not a simple feat.

The catheter manufacturers provide a list of compatible antiseptics and disinfectants in their instructions for use. However, the name of the catheter and manufacturer are not commonly found on the catheter making identification

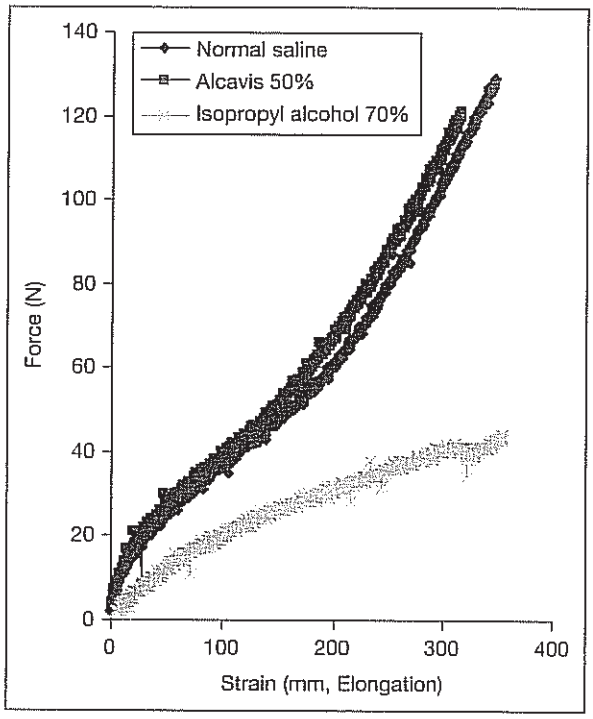

Fig. 4. Bard Hemoglide® Tecoflex® catheter in different disinfectants.

nearly impossible. Recently, some manufacturers are putting contraindicated solution markers on the actual catheter extensions to help minimize the risk of using the wrong solution and damaging the catheter.

As mentioned previously, the catheter manufacturers perform their own testing on the compatibility of their catheters with different solutions. This testing follows the ISO 10555–1 standards and consists of measuring the force that is required to break a catheter at each segment, separately. The minimum force acceptable is a force between 3 and 15 N, dependent on outside diameter of test piece. To evaluate the affects of disinfectants, the catheters are tested after being placed in solution for either extended periods of time, ex. 48 h, or placed in solution for 10 min and then removed with this step repeated every other day for 60 days, simulating actual use.

Since it has already been proven, by the dialysis catheter manufacturers, that ExSept and Alcavis 50 ESH are compatible solutions with all types of materials, this study aimed to evaluate the physical affects of different solutions

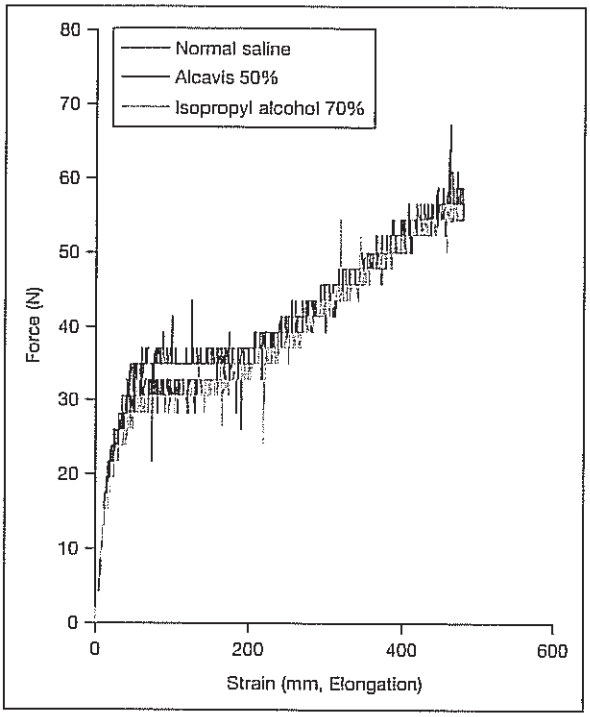

Fig. 5. Bard Hickman® Silicone catheter in different disinfectants.

on the different catheter materials. This was performed by soaking the catheters for 48 h in solution, then rinsing with saline and recording the displacement to force curves for different catheters and materials. A possible limitation of this study is that the catheters were placed in solution and filled with the solution for a period of 48 h. Normally, the antiseptic or disinfectant is in contact with the catheter for a period of not more than 10 min and then air dried. This step is then repeated every other day for as long as the catheter is in place. In addition, the inner lumen of the catheter is rarely exposed to the antiseptic/disinfectant solution (lock solutions were not evaluated in this study). However, a 48 h soak is a similar contact time to 28,810-min exposures and is, therefore, an acceptable challenge to the catheter material.

It has been clearly demonstrated in this study that ESH solutions are the only solutions that do not alter the physical properties of any of the catheters after long-term exposure. This was evident by the less than 10% deviation in the resultant displacement vs. force curves measured compared to a saline exposed control. Alcohol was clearly compatible with silicone catheters, however appears to affect the physical properties of both polyurethane based catheters.

The Tecoflex catheters do list alcohol containing solutions as contraindicated. The Carbothane catheters, which exhibited a similar deviation when exposed to alcohol, do not list alcohol as a contraindication. This is because, even though there were physical changes with alcohol exposure, the strength of the catheter was well within the ISO guidelines. The strength of Carbothane and compatibility with different solutions was also confirmed by Ash [15].

Given that ESH solutions have been shown in this study, by the manufacturers of the dialysis catheters and by decades of historical use, to be compatible with all catheter types and all catheter materials, it would be best practice to incorporate ExSept and Alcavis 50 into routine catheter site and catheter care. ESH solutions will permit ease of mind in catheter compatibility as well as safety and effectiveness as an antiseptic and disinfectant for dialysis patients throughout the world.

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